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**TTK Biomed**  
**L I M I T E D**

H-12-13, MIDC Industrial Area, Waluj, Aurangabad - 431 136  
Telephone: 54037, Fax: 55189

**510(k) Summary**  
**Clinicare**  
**Sterile Disposable Syringes**  
**Sterile Disposable Syringes With Needles**  
**Sterile Disposable Needles**

I. General Information on Submitter:

Name: TTK Biomed Limited  
Address: H-12-13, MIDC, Industrial Area, Waluj, India 431 136  
Telephone: 54037  
Fax: 55189  
Name of Contact Person:  
Date Summary Prepared:

II. General Information on Device

Name: Clinicare Sterile Disposable Syringe  
Clinicare Sterile Disposable Syringes and Needles  
Clinicare Sterile Disposable Hypodermic Needles

Common Name: Sterile Disposable Syringe  
Sterile Disposable Syringes and Needles  
Sterile Disposable Hypodermic Needle

Classification Name: Piston Syringes  
Hypodermic Single Lumen Needle

III. Predicate Devices: Sterile Disposable Syringe  
Sterile Disposable Syringes and Needles  
Sterile Disposable Hypodermic Needle  
Becton, Dickinson & Company

IV. Description of Device: The Clinicare Needles and Syringes comply with: ISO 7886, Sterile Hypodermic Syringes for Single Use; ISO 7864, Sterile Hypodermic Needles for Single Use; ISO 594, Conical Fitting with a 6% (Luer) Paper for Syringes, Needles and Certain Other Equipment; ISO 9626 Stainless Steel Needle Tubing for Manufacture of Medical Devices; and, ISO 6009, Hypodermic Needles for Single Use.

The sterile disposable syringes are made with polypropylene. The needles are made from thin walled SS304 capillary tubes. The rubber gaskets are made from natural rubber. The barrels are lubricated with Polydimethyl Silicone.

- V. Intended Use: The Clinicare Sterile Disposable Syringes and Needles are intended to be used for general purpose injections.
- VI. Technological Characteristics of Device Compared to Predicate Device: None.
- VII. Tests for Substantial Equivalence: None.